SUMMARY OF THE
QUALITY SYSTEMS COMMITTEE MEETING
JUNE 28 - 29, 1999

The Quality Systems Committee of the National Environmental Laboratory Accreditation Conference (NELAC) met on Monday, June 28, 1999, at 1:30 p.m. Eastern Daylight Time (EDT) and on Tuesday, June 29, 1999 at 8:30 a.m. EDT as part of the Fifth NELAC Annual Meeting in Saratoga Springs, NY. The meeting was led by its chair, Mr. Joe Slayton of the U.S. Environmental Protection Agency (USEPA), Region 3. A list of action items is given in Attachment A. A list of participants is given in Attachment B. *The purpose of the meeting was to discuss proposed changes to the sections of Chapter 5 dealing with calibration, detection, air testing, demonstration of capability, microbiology, internal audits, definitions, and additional proposed changes.*

INTRODUCTION

Mr Slayton reviewed the agenda and the committee's method for processing the comments. Comments sent to the committee are addressed in the order in which they are received and assigned to a committee member for the initial response. The initial responses are reviewed by the committee and the consensus responses and rationale are attached to the minutes of the meeting at which they are discussed.

Mr. Slayton also reviewed the committee's guiding principles for reviewing comments and revising Chapter 5. The guiding principles are to ensure that the requirements of Chapter 5 have the following characteristics:

- flexible,
- auditable,
- practical and essential,
- widely applicable, and
- appropriate for the use of the data.

It was noted that appendices E, F, and G are for information purposes, are not part of the requirements, and will not be voted on at this conference.

The committee members introduced themselves and described their background. Two members terms expire as of this meeting: Ms. Sheila Meyers and Mr. Donovan Porterfield.

Section 5.9.4, Calibration

Section 5.9.4.2.1.f: It was unclear why this section on initial instrument calibration was referenced by other sections, D.1.4.c and D.5.4.c, that deal with detection limits. In addition, the term *quantitation limits*, which is used in D.1.4.c and D.5.4.c is potentially confusing because it has many different interpretations. Sections D.1.4.c and D.5.4.c were deleted and the language in 5.9.4.2.1.f was revised to specify that the lowest calibration standard must be above the detection limit.

Section 5.9..4.2.1.e: The comment was made that the requirements in this section are too flexible and should be made more prescriptive. Typically, laboratories look to the standards or requirements for initial instrument calibration criteria. The committee felt that enough quality control (QC) controls have been built into the standards to allow this level of flexibility for initial instrument calibration. In addition, it may encourage regulatory programs to develop applicable criteria.

Section 5.9.4.2.1.i: The requirement for having an initial instrument calibration point at or above the established detection limit was unclear. Having an initial calibration point at the detection limit would put it in an area where quantitation is uncertain. The phrase *at or above the established detection limit* was deleted from this section.

Section 5.9.4.2.1.d: The comment was made that the frequency for verifying initial calibration with a second source standard is not specified. The committee intended for the verification to be done with every initial calibration. The laboratory must specify the criteria for accepting the calibration.

Section 5.9.4.2.2.e: These requirements are too restrictive in allowing only two attempts to obtain a continuing instrument calibration within the established acceptance criteria. If both continuing calibrations are failed, then a new initial instrument calibration must be performed. The concern is that, especially with the more complicated instruments, several corrective actions may be needed if the first continuing calibration is failed. The analyst would want to run another continuing calibration after these corrective actions to see if they corrected the problem. Allowing only one additional continuing calibration is too restrictive. Another concern is not permitting an unlimited number of continuing calibrations to be run until, eventually, one falls within the established limits. As a compromise between these two concerns, the language in the section was revised to allow the laboratory to demonstrate performance after corrective action, with two consecutive successful calibration verifications or to perform a new initial calibration.

Appendix D.1.4, Detection Limits

Section D.1.4: The comment was made that it would be difficult for an assessor to evaluate a laboratory's method for determining a detection limit if it was not specified in a test method or regulation, and the laboratory selected the procedure. In addition, if the selected procedure is not a "recognized method" then this could cause a conflict of opinion between the assessor and the laboratory about the appropriateness of the detection limit procedure. This standard should specify the detection limit procedure(s) to use if it is not specified in the method or regulations. The committee debated this issue and felt that because the statistics involved in determining detection limits can be complicated and opinions vary greatly on the procedure to use, specifying a procedure(s) would be too difficult. In addition, this may provide incentive for regulatory programs to specify the appropriate detection limits to use.

Appendix D5, Air Testing

The efforts of the members of the Quality Systems (QS) subcommittee that developed the air testing requirements for Chapter 5 were acknowledged.

An issue was raised that this section contains requirements that apply to field activities and should not be part of the standard that applies to laboratory quality systems. The committee included these requirements because for air testing, it is common for the laboratory to also do the sample collection. Language was added to the beginning of Section D.5 that the field quality control requirements apply only to laboratories that are also collecting the samples.

Section D.5.b.E: A question was raised as to the definition of *lot of sampling media*. The desorption efficiency recovery applies to the recovery of the sample from a solid sorbent of any kind and a lot is defined as a manufacturer's lot.

Section D.5.2.1: The comment was made that there is no requirement for the amount of variability allowed between duplicates, only that duplicates be run. The basic quality control measures in the chapter require the laboratory to record the duplicates and evaluate these data.

Section D.5.4.a: To be consistent with Section D.1.5 the examples of components for which spiking solutions are not available, will be deleted from this section also.

Ethics, Section 5.5.2.u, 5.6.2.c and h

The committee developed these sections in response to comments received about addressing ethical and legal responsibilities.

A comment was made that the language is too negative, has a "big brother" tone, and that most laboratory personnel are already aware of the consequences of fraud or illegal activities.

Several comments were made in support of this new language and the following specific comments were made:

- This provides an auditable requirement which is that laboratories must have a policy or program in place for educating and training personnel in their ethical and legal responsibilities including potential punishments and penalties. This language could also benefit the laboratory employee in a situation where they may be pressured to "cut corners" in their work.
- It is a good idea to put the responsibility for this on the laboratories, which is where it belongs. It is not a guarantee of preventing fraud but it makes laboratory personnel aware of the consequences of fraudulent or illegal activities.
- States or regulating bodies should have training in this area for laboratory owners or operators because, based on the commenters' experience, illegal activities may involve owners and operators.
- In cases where fraud or illegal activity is suspected, prosecuting these laboratories may be easier if these requirement are in place.
- The committee may want to phrase the requirements in a more positive tone so that it is viewed more favorably at the laboratory level.

Appendix C, **Demonstration of Capability and Sections 5.10.2.1, 5.6.2**

Section 5.10.2.1.a: The meaning of *actual sample spike results* and the chronology of events in this requirement are not clear. This was added for laboratories that have been repeatedly analyzing samples in the same matrix and primarily only analyze samples in this matrix so that they may use the historical matrix spikes data for demonstration of capability.

The comment was made that the issues of analyst proficiency, method validation, and demonstration of capability are confused in these sections. It should be clarified that Appendix C, Demonstration of Capability, addresses laboratory demonstration of confidence, which fits with the glossary definition of demonstration of capability, and not analyst demonstration of capability, which is addressed in 5.6.2. The difficulty is that these issues are related and all need to be part of the requirements. Changing the definition of demonstration of capability may address this or another approach would be to break out the requirements for the laboratories versus the analysts. Also, Appendix C should be worded so that it applies to all test methods and not just those mandated or required by regulation.

Appendix C, Certification Statement, Item 5: The term *raw* should be eliminated from the phrase *raw data*. The term raw data can be misconstrued to include a wide range of data and records, which could result in a heavy record keeping requirement on the laboratory. The key is to maintain data, not to validate the analysis but to support the analysis.

Also, the requirement should be for the data to be maintained *by* the facility and not *at* the facility, which could become a record storage problem. However, the data can be maintained electronically so data storage at the laboratory may not be a problem. In addition, auditing can be difficult if the laboratory does not have the data on site.

Section 5.10.2.1.a.2: This section refers to Appendix E, which is currently not part of the standard. The comment was made that accrediting authorities should recognize test methods developed through Performance Based Measurements Systems (PBMS) and Appendix E, which covers PBMS, be adopted as part of the standard.

Section 5.6.2.c.4.iii: These requirements for blind performance sample analysis may conflict with the requirements of the methods which are used as examples.

Section 5.10.2.1.a.1 and a.2: These two sections were deleted to avoid confusion. Since there are no requirements for PBMS (Appendix E is for informational purposes only), there is no need to have a reference to Appendix E and a separate reference to Appendix C.

Section 5.10.2.1.a.3: This section will be incorporated into the paragraph in 5.10.2.1.a to avoid redundancy.

Section 5.10.2.1.c: This should be reworded (reference to Appendix E) to be consistent with revised paragraph a. In addition, other references to Appendix E in the chapter should be reviewed to make sure it is appropriate.

Appendix D.3, Microbiology, Section 5.9.4.1.f

Section D.3.6.c: The examples of characteristics of water quality to test should include heterotrophic bacteria. In addition, the requirement for testing water should apply all the time, not just when required by the test method.

Section D.3.6.f: The question was raised as to how a "lot" and "laboratory detergent" are defined. The requirements should be that laboratories use detergent of laboratory grade and perform an inhibitory residue test at least once per year. Another comment was made that the requirement should be for a laboratory to test each lot of laboratory detergent and not to test the detergent every year. A manufacturer's certificate of inhibitory residue testing is an alternative to the laboratory performing the test. Also, another laboratory could perform this test.
The requirement for requiring laboratory grade detergent may be more appropriate for Section D.3.8.

Section D.3.8: The comment was made that guidance should be provided on how much data (e.g., how may months of data on autoclave runs) should be maintained to meet these requirements.

Section 5.9.4.1.f and g: The requirements should include recording the cycle length and/or sterilization time.

Section 5.5.3.1, Internal Audits

No comments were made on this section.

Appendix B, Definitions

Appendix B, including changes, will be removed from Chapter 5 and placed in Chapter 1 as a unified glossary.

Definition of Batch: The requirement that the maximum time for a preparation batch is only 24 hours could place a heavy burden on small laboratories for analyzing quality control samples. The committee understood that this may require extra work, especially for small laboratories, but associating the quality control samples with the measurement samples is an essential quality control item.

It was pointed out that the matrix spike is not a batch acceptance criteria but is intended to give the analyst an indication of how the method is working in that particular matrix.

Definition of Holding Times: This definition should include the time of sample collection as the starting time for the holding time.

Editorial changes were made to definitions of other terms.

ADDITIONAL PROPOSED CHANGES

Section 5.1: Additions to this section were intended to clarify the concept of what is considered more stringent versus what is simply different between test methods or regulations. When it is not clear which is more stringent, then the regulation or required test method should be used.

Section 5.4.2.e: The question was raised as to whether the ratio of supervisory to non-supervisory personnel is auditable. In some cases the laboratory may not have control over this because of personnel requirements. This requirement was taken from the ISO Guide.

Section 5.5.2: No comments were made on this section.

Section 5.5.3.2: No comments were made on this section.

Section 5.5.4: Editorial changes were made on this section.

Section 5.6.1: No comments were made on this section.

Section 5.6.2.c.3.v: The meaning of *statistically indistinguishable result* should be more clearly defined and made more auditable. This terminology may have a very specific meaning to statisticians.

Section 5.6.2.b, Note: The comment was made that work cells may be operationally different that what is defined in this section. For example, a work cell could consist of 5 analysts who perform the same step in analytical procedures.

The definition of the work cell is not intended to cover a situation where more than one analyst performs the entire analytical procedure. In this situation, each analyst needs to demonstrate capability initially.

This requirement was worded to allow for operational differences that exist in different laboratories in terms of the work cell. Also, the committee wanted to avoid requiring every combination of analysts in the work cell demonstrate capability.

The note in 5.6.2.b will be moved to the end of the section so its clear that all the items in this section apply to the work cell.

Attachment A

ACTION ITEMS
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Item No.	Action	Date to be Completed
1.	Joe Slayton to update Rev. 5.11 (following N5) with items the committee has proposed since 4/29/99.	7/11/99

Attachment B

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QUALITY SYSTEMS COMMITTEE MEETING
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